

11/14/2019

John McKenzie, CEO
Wickham Laboratories Ltd.
Hoeford Point
Barwell Lane
Gosport Hampshire PO130AU, UK

Dear Mr. McKenzie,

We are enclosing a copy of the establishment inspection report (EIR) for the inspection conducted at your premises at Hoeford Point Barwell Lane, Gosport Hampshire PO130AU, UK on 09/23/2019 to 09/25/2019 by investigator Guerlain Ulysse on behalf of the U.S. Food and Drug Administration (FDA). When the Agency concludes that an inspection is "closed," under 21 C.F.R. 20.64 (d) (3), it will release a copy of the EIR to the inspected establishment. This procedure is applicable to EIRs for inspections completed on or after April 1, 1997. For those inspections completed prior to the above date, a copy of the EIR may still be made available through the Freedom of Information Act (FOIA).

The Agency continually works to make its regulatory process and activities more transparent to the regulated industry. Releasing this EIR to you is part of this effort. The copy being provided to you comprises the narrative portion of the report; it may reflect redactions made by the Agency in accordance with the Freedom of Information Act (FOIA) and 21 CFR Part 20. This, however, does not preclude you from requesting additional information under FOIA.

If there is any question about the released information, feel free to contact Douglas Kovacs at 973 331-4936 douglas.kovacs@fda.hhs.gov

Sincerely,

**Douglas C.
Kovacs -S**

Digitally signed by Douglas C. Kovacs
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Date: 2019.11.14 11:03:55 -05'00'

Douglas Kovacs
Supervisory Consumer Safety Officer
Office of Pharmaceutical Quality Operations
Division 1, Investigations Branch 1
Office of Regulatory Affairs
U.S. Food and Drug Administration